FLUTICASONE PROPIONATE- fluticasone propionate spray, metered
Hi-Tech Pharmacal Co., Inc.

Drug Facts

Active ingredient

Fluticasone propionate (glucocorticoid) 50 mcg (in each spray)

Purpose

Allergy symptom reliever

Keep Out of Reach of Children

Uses

Temporarily relieves these symptoms of hay fever or other upper respiratory allergies:

■ nasal congestion

■ runny nose

■ sneezing

■ itchy nose

■itchy, watery eyes

Warnings

Only for use in the nose. Do not spray into your eyes or mouth.

Do Not Use

■ in children under 4 years of age

■ to treat asthma

■ if you have an injury or surgery to your nose that is not fully healed

■ if you have ever had an allergic reaction to this product or any of the ingredients

Ask a doctor before use if you

have or had glaucoma or cataracts

Ask a doctor or pharmacist before use if you are taking

■ medicine for HIV infection (such as ritonavir)

■ a steroid medicine for asthma, allergies or skin rash

■ ketoconazole pills (medicine for fungal infection)

When using this product

■ the growth rate of some children may be slower

■ stinging or sneezing may occur for a few seconds right after use

■do not share this bottle with anyone else as this may spread germs

■ remember to tell your doctor about all the medicines you take, including this one

Stop use and ask a doctor if

■ you have, or come into contact with someone who has, chicken pox, measles or tuberculosis

■ your symptoms do not get better within 7 days of starting use or you get new symptoms such as severe facial pain or thick nasal discharge. You may have something more than allergies, such as an infection.

■ you get a constant whistling sound from your nose. This may be a sign of damage inside your nose.

■ you get an allergic reaction to this product. Seek medical help right away.

■ you get new changes to your vision that develop after starting this product

■ you have severe or frequent nosebleeds

Pregnancy or Breast Feeding

ask a health professional before use.

Keep Out of Reach of Children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

■ read the Quick Start Guide for how to:

■ prime the bottle

■ use the spray

■ clean the spray nozzle

■ shake gently before each use

■ use this product only once a day

■ do not use more than directed

ADULTS AND CHILDREN 12 YEARS OF AGE AND OLDER

■ Week 1 – use 2 sprays in each nostril once daily

■ Week 2 through 6 months – use 1 or 2 sprays in each nostril once daily, as needed to treat your symptoms

■ After 6 months of daily use – ask your doctor if you can keep using

CHILDREN 4 TO 11 YEARS OF AGE

■ the growth rate of some children may be slower while using this product. **Children should use for the shortest amount of time necessary to achieve symptom relief. Talk to your child's doctor if your child needs to use the spray for longer than two months a year.**

■ an adult should supervise use

■ use 1 spray in each nostril once daily

CHILDREN UNDER 4 YEARS OF AGE

■ **do not use**

Other information

■ **TAMPER EVIDENT:** Do not use if plastic sleeve is torn or broken. Under the cap and nozzle, each bottle has an aluminum seal around bottle neck. **Do not use if any of these features are torn or damaged.**

■ you may start to feel relief the first day and full effect after several days of regular, once-a-day use

■ store between 4° and 30°C (39° and 86°F)

■ keep the label and enclosed materials. They contain important additional information.

Inactive Ingredients

benzalkonium chloride, carboxymethylcellulose sodium, dextrose, microcrystalline cellulose, phenylethyl alcohol, polysorbate 80, and purified water

Questions or comments

Call toll-free 1-**800-262-9010** weekdays (9:00 am- 5:00 pm)

What problems can Fluticasone Propionate Nasal Spray help with?

Fluticasone Propionate Nasal Spray helps relieve a broad range of uncomfortable symptoms like congestion, runny nose, sneezing, itchy nose and itchy eyes.

These symptoms can be triggered by allergens like pollen, mold, dust and pet dander.

Manufactured by:

Hi-Tech Pharmacal Co., Inc.

Amityville, NY 11701

Rev.968:00 09/17

Package/Label Principal Display Panel

AKORN

* Compare to the active ingredient in Flonase®

NDC 50383-968-16

Fluticasone Propionate Nasal Spray (Glucocorticoid), 50 mcg Per Spray

Allergy Symptom Reliever Nasal Spray

24 Hour Relief of:

■ Itchy, Watery Eyes

■ Nasal Congestion

■ Runny Nose

■ Itchy Nose

■ Sneezing

NEW: FULL PRESCRIPTION STRENGTH

NON DROWSY

24 HOUR RELIEF

120 METERED SPRAYS

0.54 fl oz (15.8 mL)

FLUTICASONE PROPIONATE

fluticasone propionate spray, metered

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50383-968
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FLUTICASONE PROPIONATE (UNII: O2GMZ0LF5W) (FLUTICASONE - UNII:CUT2W21N7U)	FLUTICASONE PROPIONATE	50 ug

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**

1	NDC:50383-968-18	1 in 1 CARTON	04/18/2019	
1		60 in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:50383-968-16	1 in 1 CARTON	04/18/2019	
2		120 in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
3	NDC:50383-968-36	2 in 1 CARTON	04/18/2019	
3		60 in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
4	NDC:50383-968-37	2 in 1 CARTON	04/18/2019	
4		120 in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
5	NDC:50383-968-38	3 in 1 CARTON	04/18/2019	
5		120 in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208024	04/18/2019	

Labeler - Hi-Tech Pharmacal Co., Inc. (117696873)

Registrant - Akorn Operating Company LLC (117693100)

Establishment

Name	Address	ID/FEI	Business Operations
Hi-Tech Pharmacal Co., Inc.		117696873	MANUFACTURE(50383-968)

Revised: 9/2020 Hi-Tech Pharmacal Co., Inc.